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Workflow and intervention times of MR-guided focused ultrasound – Predicting the impact of new techniques

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ABSTRACT

Magnetic resonance guided focused ultrasound surgery (MRgFUS) has become an attractive, non-invasive treatment for benign and malignant tumours, and offers specific benefits for poorly accessible locations in the liver. However, the presence of the ribcage and the occurrence of liver motion due to respiration limit the applicability MRgFUS. Several techniques are being developed to address these issues or to decrease treatment times in other ways. However, the potential benefit of such improvements has not been quantified. In this research, the detailed workflow of current MRgFUS procedures was determined qualitatively and quantitatively by using observation studies on uterine MRgFUS interventions, and the bottlenecks in MRgFUS were identified. A validated simulation model based on discrete events simulation was developed to quantitatively predict the effect of new technological developments on the intervention duration of MRgFUS on the liver. During the observation studies, the duration and occurrence frequencies of all actions and decisions in the MRgFUS workflow were registered, as were the occurrence frequencies of motion detections and intervention halts. The observation results show that current MRgFUS uterine interventions take on average 213 min. Organ motion was detected on average 2.9 times per intervention, of which on average 1.0 actually caused a need for rework. Nevertheless, these motion occurrences and the actions required to continue after their detection consumed on average 11% and up to 29% of the total intervention duration. The simulation results suggest that, depending on the motion occurrence frequency, the addition of new technology to automate currently manual MRgFUS tasks and motion compensation could potentially reduce the intervention durations by 98.4% (from 256 h 5 min to 4 h 4 min) in the case of 90% motion occurrence, and with 24% (from 5 h 19 min to 4 h 2 min) in the case of no motion. In conclusion, new tools were developed to predict how intervention durations will be affected by future workflow changes and by the introduction of new technology.

1. Introduction

The non-invasive ablation of tumours in the human body is a goal that is becoming reality with the introduction of MRI-guided focused ultrasound surgery (MRgFUS). In focused ultrasound surgery (FUS), a beam of acoustic energy is transmitted into the tissue of the human body by a FUS-transducer, and is concentrated in a focal point for about 15–45 s. Such a pulse is called a 'sonication' and firing such a pulse at a target spot is called 'sonicating'. At the focal point, the tissue heats up to the point that it becomes necrotic, whereas outside the focal point, the tissue remains undamaged [1]. MRI is a valuable modality for target definition, intervention planning, and closed-loop control of the acoustic energy deposition during FUS. In addition, MRI provides accurate, real-time temperature maps. Such thermal feedback facilitates

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intervention monitoring, since it allows for the immediate evaluation of the temperature in the targeted volume, which helps to minimise the risk of damaging the adjacent tissues [2–4].

Over the last two decades, MRgFUS has become an attractive non-invasive treatment for both benign and malignant tumours. MRgFUS has been approved by the US Food and Drug Administration (FDA) for uterine fibroid treatment, and is in ongoing clinical or pre-clinical trial for the treatment of breast, liver, prostate, and brain cancer, and for the palliation of pain in bone metastasis [5,6]. There have been attempts to treat liver tumours with MRgFUS in pre-clinical trials [7,8] and in clinical trials [9,10]. MRgFUS enables the treatment of parts of the liver that are poorly accessible for conventional surgery, and may even reduce the need for conventional surgery and its accompanying risks. However, despite the potential benefits of MRgFUS, there are two major challenges to be overcome if it is to be broadly applied on the liver: the presence of the ribcage surrounding the liver, and the liver motion due to respiration (or coughing or sneezing).

The bone tissue of the ribs would absorb most of the acoustic energy, blocking the acoustic beam path towards liver tumours and causing unwanted, potentially damaging heating of the skin and ribs [11]. To avoid sending the acoustic energy through the ribs, several studies have focused on multiple-element ultrasonic transducers in which elements can be selectively switched on or off depending on their beam path towards a target in the liver [12–14]. Respiratory motion causes a cyclic shift in liver tumour position, resulting in healthy tissue rather than the tumour being heated if no compensation is made in the FUS beams over the breathing cycle. The liver movement can also induce motion artefacts in the MR and temperature maps [15]. Voluntary breath-holding, gating techniques, and controlled breathing during general anaesthesia have all been suggested to prevent organ movement during sonications [16]. Reference-less MR thermometry and active steering of the FUS beam have been used to compensate for organ motion [17–19].

MRgFUS procedures are currently rather time-consuming. Improvement of the time- and cost-efficiency of MRgFUS is sought in technological developments, including the automation of procedure planning and execution and the automation of image segmentation [14].

The authors were aware that in order to develop necessary technology and tools for MRgFUS on the liver and other moving organs, it is crucial to fully understand the workflow of MRgFUS. By identifying the bottlenecks in the current workflow it would be easier to properly improve and optimise the current MRgFUS procedures. Furthermore, if a quantitative estimate could be made of the benefits that can be obtained by introducing new technologies, it would be possible to focus research efforts more efficiently. Despite ongoing developments aimed at enabling MRgFUS for moving abdominal organs, neither detailed workflows of MRgFUS nor quantitative estimates of the potential benefits of new technology on the workflow could be found in the literature. Therefore, the aim of this study was:

- to estimate quantitatively the workflow improvements that can be achieved by the key technologies that are currently being developed for MRgFUS.

To do so, it was necessary to first:

- establish the detailed workflow of current clinical practice in MRgFUS,
- identify the bottlenecks in current clinical practice in MRgFUS, and
- build and validate a workflow simulation model for MRgFUS.

2. Methods

2.1. Workflow observations

As technologies required for enabling safe MRgFUS on the liver are still being developed, MRgFUS has not yet been cleared for liver treatments. The workflow of current clinical practice in MRgFUS was therefore determined through observations of the well-established MRgFUS treatment of uterine fibroid.

A working version flowchart ('observation flowchart') of the MRgFUS workflow was developed on the basis of observations and time registrations during:

- three uterine MRgFUS interventions in the Policlinico Umberto I, Rome, Italy,
- one uterine MRgFUS intervention in the Amper Klinikum, Dachau, Germany, and
- four iteration sessions with clinical experts (surgeons and interventional radiologists), clinical FUS experts and workflow experts within the consortium of the European FP7 "FUSIMO" project (www.fusimo.eu, accessed 13 March 2014).

The observation flowchart was used during 12 uterine MRgFUS intervention observations to make detailed registrations of the durations and occurrence frequencies of most actions and decision points described in the observation flowchart. These observation data were used to verify that the developed workflow agrees with clinical practice, and to obtain probability distributions for the workflow simulations that are described in Section 2.3. Six of those observations were conducted in the clinic in Rome, and six were conducted in the clinic in Dachau. Anonymous patient data, namely age, anamnesis, build, and names of the interventional radiologist and his support team, were gathered for each observation. These data were collected to assure that the patient group was reasonably homogeneous and to allow checking whether any potential workflow deviations were related to the patient demographics. Noticeable events or situations were noted during the observations and included in the data files. In order to support the observation data, a questionnaire was completed by the interventional radiologists to obtain estimates of the likelihood of specific events occurring.

Some actions and decision points described in the observation flowchart always followed automatically, and often instantly, after specific other decision points or actions and had such short durations that registering individual durations was infeasible and unnecessary. For such actions and decision points a duration of one second was used.

All observations and registrations were done by the same observer (author AJL). All observed MRgFUS interventions were uterine fibroid interventions performed by highly experienced interventional radiologists. All interventions were performed using ExAblate (InSightec, Haifa, Israel) FUS equipment and software, further referred to as "the FUS-software". A preliminary ethics review was done at the departmental level and according to the applicable guidelines, the studies were exempt from a full ethics board review in either of the two hospitals. If the study is to be repeated later or elsewhere, a complete ethics review may be necessary.

Descriptive statistics were obtained from the observation data to identify bottlenecks in the MRgFUS workflow, and to discover which actions and phases in the workflow were the most time-consuming. For reasons of clarity and comprehensibility, in this report detailed quantitative results are given only on the phase levels and not on the level of individual actions or decision points.